Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

November 20, 2025 | 1:00pm–3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To discuss the status of proposal discussions and the path forward for financial subgroup negotiations, and to begin discussion of the technical change proposals from FDA.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Steve Berman	BIO
Angela Granum	CDER	Carl Garner	PhRMA (Eli Lilly)
Kate Greenwood	OCC	Kelly Goldberg	PhRMA
Christine Hunt	OCC	Kristy Lupejkis	PhRMA
Rebecca Kemp	CBER	Alison Maloney	PhRMA (Bayer)
Joshua Kirk	OO/OFBA	Drew Sansone	BIO (Alkermes)
Andrew Kish	CDER		
Stacy Yung	CDER		

MEETING SUMMARY

The subgroup followed up on the planning conversation from the prior meeting to discuss how to proceed. The subgroup then discussed FDA's technical change proposals.

Follow Up Discussion

Industry indicated it wanted to find a path forward on the core aspects of financial negotiations before continuing on to other proposal topics. Industry noted that it would need data to help support an assessment of potential administrative efficiencies and referred to a data call it had sent. FDA noted the data call was very detailed and said that at this point in the negotiation process, FDA will only be able to consider data requests that are focused on moving specific proposals forward. Industry said that it did not have data to formulate a proposal and would look to FDA to develop a proposal. FDA said it could take that back and look at how to approach assessing potential savings from administrative efficiencies.

FDA stated, however, that it would not be able to bring counterproposals to Industry regarding the capacity planning adjustment (CPA) and the inflation adjustment, noting that FDA fundamentally rejected Industry's premise that PDUFA is experiencing "uncontrolled growth." FDA noted it already shard data explaining the increases in program funding and reiterated the data doesn't support Industry's premise. As such, FDA will not be able to engage in brainstorming with Industry on these proposals under this premise. FDA noted there was a potential path forward involving administrative efficiencies and technical modifications and the subgroup discussed what data may be helpful.

Following a brief caucus, Industry reopened the meeting by stating that they wanted to move forward in a way that would enable FDA to maintain a stable and sustainable program and to staff in-line with the strategic intent of FDA's leadership and noted that it would shift its framing away from the "uncontrolled growth" narrative. Industry noted they would need some data to help support thinking on potential administrative efficiencies and on how to approach potential technical modifications rather than removing the CPA.

The subgroup discussed what data may be helpful to move these proposals forward. FDA committed to providing relevant data as feasible.

Technical Changes

Industry asked whether the technical change proposals are truly technical changes and suggested that the "technical change" framing may need to be revisited.

Technical Changes – Program Fee Eligibility Date

Under FDA's proposal, approved products would be eligible for the program fee based on their status as of April 1st rather than October 1st.

FDA noted that the program fee eligibility date proposal would reduce administrative processes for both Industry and FDA. Currently, products are liable for the program fee as of their marketing status on October 1 and the fees are due on that same day. As such, invoices must be sent in advance and when there are then changes to product status or if there are waiver requests, the sponsor may have to pay the original invoice and then request a refund. FDA stated that this process is onerous for both FDA and industry and would be mitigated under FDA's proposal. Additionally, this proposal would improve the predictability of the program fee collections as there would be more certainty regarding the total billable population.

Industry asked clarifying and legal questions and FDA answered them as appropriate. Industry indicated it would review further.

Next Steps

The goals for the next meeting on December 2nd will be to review and discuss the planned data call response.